

Serial No.: 10/735,098

Group Art Unit No.: 1645

This is a restriction, not a species election because each sequence represents a different product.

Group III. Claims 43, 51, 52, and 55, drawn to isolated antibodies and a kit comprising said antibodies.  
NOTE: Applicants must elect a single antibody immunospecific for a polypeptide sequence from SEQ ID NOS: 2, 4, 6, 8 and 10. This is a Restriction, not a species election because each sequence represents a different product.

Group IV. Claim 44, drawn to a method for identifying compounds through the use of a polypeptide.  
NOTE: Applicants must elect a single sequence from SEQ ID Nos: 2, 4, 6, 8 and 10. This is a Restriction, not a species election because each sequence represents a different product.

Group V. Claim 50, drawn to a method of vaccinating using a polynucleotide. NOTE: Applicants must elect a single sequence from SEQ ID Nos: 1, 3, 5, 7 and 9. This is a Restriction, not a species election because each sequence represents a different product.

#### REMARKS

Applicants wish to make a provisional election of Group I, i.e., claims 35-39, and 53, with traverse. Applicants' traversal is based on PCT Rule 13.2 which states that unity of invention shall be fulfilled "When there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". Applicants respectfully direct the Examiner to Annex B of the PCT Rules, Part 2 (Examples Concerning Unity of Invention), Example 17 (MPEP AI-60), which describes "Protein X" and "DNA sequence encoding protein X". Unity between the claims is accepted for "the protein and the DNA sequence exhibit corresponding technical features". That is, "expression of the DNA

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sequence in a host cell results in the production of a protein which is determined by the DNA sequence". If the Examiner is not persuaded by the arguments noted above, Applicants retain the right to file divisional applications directed to the non-elected subject matter should the restriction requirement become final.

Applicants are further required to elect a single sequence from the Group. That is, an additional restriction must be made to a single sequence selected from SEQ ID Nos: 1, 3, 5, 7 and 9. The Examiner notes that this is not a species election because each sequence represents a different product.

Applicants strongly oppose the further restriction but provisionally elect SEQ ID No: 1 (*N. meningitidis* strain BNCV) with traverse. Applicants respectfully request the withdrawal or a waiver of this further restriction for the following reasons:

*The Sequences in Group I encode homologues of the same protein.* That is, SEQ ID Nos: 1, 3, 5, 7 and 9 all encode lactoferrin binding protein B (LbpB) from different isolates of *N. meningitidis* - see Example 7 of the specification. Figure 9 illustrates the homology between the different LbpBs (i.e., common structural features between SEQ ID Nos: 1, 3, 5, 7 and 9). Example 10(D) teaches that various LbpBs can provide cross-immunoprotection against heterologous strains of *N. meningitidis*. That is, all 5 sequences encode a closely related family of lactoferrin binding protein Bs, with homologous function. Applicants respectfully submit that there is a common general inventive concept between SEQ ID Nos: 1, 3, 5, 7 and 9, and as such this clearly fulfills the requirement for unity of invention.

*There is no a lack of unity between SEQ ID Nos: 1, 3, 5, 7 and 9 according to the PCT International Searching Authority.* The regulations state that U.S. national stage applications filed under 35 U.S.C. 371 are subject to unity of invention practice in accordance with 37 CFR 1.475 and 1.499 (see MPEP 1896, 1895.01(D), and 801). No unity of invention objections were raised against the corresponding claims during PCT examination. Furthermore, no error was alleged by the Patent Office regarding the PCT unity of invention determination, and thus there is no basis to disregard the findings of the PCT International Search Authority.

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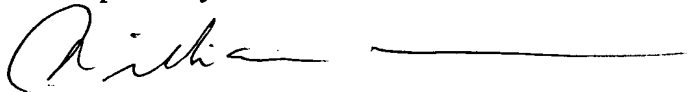
*A partial waiver of the restriction requirement (CFR 1.475 or 37 CFR 1.141) is available for Nucleotide Sequences.* According to MPEP sections 1850, and MPEP 803.04, even if the Examiner is of the view that nucleotide sequences are structurally distinct chemical compounds and are thus unrelated to each other, the regulations clearly state that a *reasonable* number of sequences that constitute independent and distinct inventions (which Applicants maintain is not the case here) can be examined at the same time. Applicants respectfully submit that a search of 5 related sequences is not unreasonable, it does not create an undue burden on the Office, and it facilitates the advancement of the biotechnology arts (e.g., a seven-way restriction (e.g., Groups I-VII) for one family of proteins is far less burdensome upon any Applicant than a thirty five-way restriction (i.e., 7 Groups x 5 sequences each).

The foregoing argument that sequences in Group I encode homologues of the same protein was presented by the Applicants in a Response to Restriction Requirement filed in parent application serial number 10/485,760, and was accepted by the Examiner.

Hence, Applicants respectfully request that the second restriction requirement to a single SEQ ID NO. be waived or withdrawn.

Applicants retain the right to file divisional applications directed to the non-elected subject matter should the restriction requirement become final.

Respectfully submitted,



William T. Han  
Attorney for Applicants  
Registration No. 34,344

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-5263  
Facsimile (610) 270-5090  
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